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SUMMARY OF SAFETY AND EFFECTIVENESS

The following summary is provided pursuant to Section 513(I)(3)(A) of the Federal Food, Drug and Cosmetic Act.

A. Applicant Information

- ***Submitter***: Orthomerica Products, Inc. 505 31st Street, P.O. Box 2927, Newport Beach, CA 92659, FDA Establishment Registration Number 1058152.
- ***Contact***: David C. Kerr, Chief Executive Officer, Telephone: (949) 723-4500, Facsimile: (949) 723-4501; Shannon R. Schwenn, Vice President, Manufacturing, Telephone: (407) 290-6592, Facsimile: (407) 290-2419, E-Mail: sschwenn@orthomerica.com.
- ***Summary Date***: February 8, 2002

B. Device Name and Classification

- ***Proprietary Name***: STARlight Cranial Remolding Orthosis
- ***Common or Usual Name***: Cranial remolding orthosis
- ***Classification Name***: Cranial orthosis
- ***Predicate Device***: STARband™ Cranial Remolding Orthosis, K001167, classified under 21 CFR § 882.5970

C. Device Description

The STARlight is a cranial remolding orthosis used to treat abnormal head shape (clinically referred to as positional or deformational plagiocephaly) in infants aged three to 18 months. The orthosis provides total contact over the protruding areas of deformity and leaves room for growth over those areas of the infant's head that were flattened during deformation. The STARlight cranial remolding orthosis is available only when prescribed by a physician.

The orthosis is custom made for each patient from a mold or three-dimensional scan of the infant's head initially prepared by the treating clinician. The mold or electronic file is then sent to Orthomerica where it is used to create the orthosis. Each orthosis is comprised of a plastic shell, either in full form with no openings, side-opening, or with bi-valved design and sliding/overlap closure system. The treating clinician modifies and adjusts the orthosis for a precise fit, and monitors its use throughout the treatment program to ensure that no severe adverse reactions occur.

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D. Intended Use

The STARlight cranial remolding orthosis is intended for medical purposes to provide total contact over prominent regions and to provide voids over depressed regions of an infant's cranium in order to improve cranial symmetry and/or shape in infants from three to 18 months of age, with moderate to severe non-synostotic deformational plagiocephaly, including infants with plagiocephalic-, brachycephalic- and scaphocephalic-shaped heads.

E. Comparison to Predicate Device

The STARlight and its predicate device are very similar with respect to patient care, instructions for use, safety and effectiveness, and special controls. The most significant difference between the two products is that the STARlight cranial remolding orthosis is offered in three design variations and is fabricated from either clear Surlyn® or Clear Co-Polyester plastic. The full form design has no openings; the single-opening has a proximal hole and an opening on the side; and the bi-valved design is equipped with a sliding/overlap closure system to ensure that inappropriate levels of pressure are not exerted on the infant's head. The sliding/overlap closure system is formed from materials commonly used in many types of orthoses and is attached on the external surface of the STARlight and therefore does not present new safety concerns.

The indications for use of the STARlight are the same as those claimed by the predicate device.

F. Performance Data

The effectiveness of the STARlight cranial remolding orthosis has been established by numerous studies. Researchers studying the effects of treatment with cranial orthoses on infants have concluded that the devices are effective in correcting abnormal head shape, without evidence of relapse follow treatment. In addition, treatment with cranial remolding orthoses is reported to improve the results of surgery in severe cases to such a degree that an ordinarily necessary additional surgical treatment can be avoided. The most comprehensive assessment of cranial orthoses monitored the treatment of more than 750 infants over a span of nearly ten years. Results were recorded at the end of the treatment period and again at 12, 18 and 24 month follow-ups. The study documented complete or near complete correction of asymmetry for a wide variety of head shapes.

The safety of the cranial remolding orthoses is established under standard biocompatibility assessments and other tests. The biocompatibility assessments reveal that the orthosis is not expected to adversely affect infants under intended conditions of wear. Specifically, the materials used in the orthosis are not reported to cause skin irritation or any toxic harms. In addition, the product is designed to avoid improper slippage or harmful levels of pressure. The internal surface and edges of the orthosis are smooth and does not pose threats of agitation or abrasion.

G. Summary

The safety and effectiveness data submitted to FDA establishes that STARlight cranial remolding orthosis is safe and effective for its intended use and is substantially equivalent to applicable predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 0 2007

Orthomerica Products, Inc.
% Ms. Deanna Fish
6333 North Orange Blossom Trail
Orlando, Florida 32810

Re: K021207
Trade/Device Name: Starlight
Regulation Number: 882.5970
Regulation Name: Cranial Orthosis
Regulatory Class: Class II
Product Code: OAN
Dated: April 9, 2002
Received: April 16, 2002

Dear Ms. Fish:

This letter corrects our substantially equivalent letter of July 9, 2002.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 (see http://www.fda.gov/cdrh/organiz.html#OC for OC organization structure). Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Barbara Melkerson for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K021207

Device Name: STARLIGHT

Indications for Use:

The STARlight is available by prescription only and intended for use in infants from three to 18 months of age with moderate to severe non-synostotic positional plagiocephaly, including infants with plagiocephalic-, brachycephalic- and scaphocephalic-shaped heads by applying mild pressure to prominent regions of the infant's cranium in order to improve cranial symmetry and/or shape.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K021207